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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,662	11/13/2003	Brian D. Voyce		2610

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EXAMINER	
FORD, VANESSA L	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,662	VOYCE, BRIAN D.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the Restriction requirement filed on July 7, 2004 is acknowledged. Applicant's election of Group II, claims 18-30, is acknowledged. Claims 1-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification Objections

2. Claims 18 and 24 are objected to for the following informalities: Claims 18 and 24 require periods (.) at the end of the sentence.

3. Claim 21 and 27 are objected to for the following informalities: Claims 21 and 27 recite, "... in which the blood is monitor..." should be changed to "... in which the blood is monitored..."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18-30 recite, "binding means associated". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "binding means associated" cannot be ascertained. Clarification as to the meaning of this term is required.

5. Claims 18-30 recite "at least a portion". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "at least a portion" cannot be ascertained. Clarification as to the meaning of this term is required.

6. Claims 18-30 recite "significant risk". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "significant risk" cannot be ascertained. Clarification as to the meaning of this term is required.

7. Claims 18-30 recite "acceptable risk level". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "acceptable risk level" cannot be ascertained. Clarification as to the meaning of this term is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 18-30 are rejected under 35 U.S.C. 102(b) as anticipated by Davidner et al, *(U.S. Patent No. 6,193,681 B1, published February 27, 2001).*

Claims 18-30 are drawn to a method for treating a patient having a severe peripheral bacterial infection comprising connecting the patient's peripheral system to an extracorporeal adsorption container having an inlet means and an outlet means for circulating blood in a whole or separated form; a solid support disposed and confined within the container; and a binding means associated with the solid support that is specific for affixing an infecting bacterium that is causing the severe peripheral bacterial infection; circulating the patient's blood through the container, thereby cleansing the blood by removing at least a portion of the infecting bacterium; and returning the treated blood to the patient.

Davidner et al teach methods of treating septicemia in a patient blood comprising using an extracorporeal system which includes an anti-microbial device (see the

within the container; and a binding means associated with the solid support that is specific for affixing an infecting bacterium that is causing the severe peripheral bacterial infection; circulating the patient's blood through the container, thereby cleansing the blood by removing at least a portion of the infecting bacterium; and returning the treated blood to the patient.

Sever, Jr. teaches methods of treating patients that have severe peripheral bacterial infection with an extracorporeal adsorption device that removes foreign agents such as viruses, organic toxins, inorganic toxins, parasites, pathogens and the like from a patients blood (see the Abstract and column 4). Sever, Jr. teaches that the cleansed blood is re-transfused back into the patient (see the Abstract). Claim limitations such as "wherein any antibiotic treatment of the patient is curtailed until the infecting bacterial load has been lowered to an acceptable risk level" and "which the blood is monitored for the reduction in the level of bacteria after treatment" would be inherent in the teachings of the prior art. Sever, Jr., anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Abstract). Davidner et al teach that target molecules include endotoxins from gram-negative bacteria, exotoxins from gram-negative and gram-positive bacteria (see the Abstract). Davidner et al teach that the extracorporeal system is used to filter the blood and the filtered blood is returned to the patient (column 3). Claims limitations such as "wherein any antibiotic treatment if the patient is curtailed until the infecting bacterial load has been lowered to an acceptable risk level" and "which the blood is monitored for the reduction in the level of bacteria after treatment" would be inherent in the teachings of the prior art. Davidner et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 18-30 are rejected under 35 U.S.C. 102(b) as anticipated by Sever, Jr. *(U.S. Patent No. 5,817, 045, published October 6, 1998).*

Claims 18-30 are drawn to a method for treating a patient having a severe peripheral bacterial infection comprising connecting the patient's peripheral system to an extracorporeal adsorption container having an inlet means and an outlet means for circulating blood in a whole or separated form; a solid support disposed and confined

10. Claims 18-30 are rejected under 35 U.S.C. 102(b) as anticipated by Matson et al *(U.S. Patent No. 6, 287, 516 B1, published September 11, 2001).*

Claims 18-30 are drawn to a method for treating a patient having a severe peripheral bacterial infection comprising connecting the patient's peripheral system to an extracorporeal adsorption container having an inlet means and an outlet means for circulating blood in a whole or separated form; a solid support disposed and confined within the container; and a binding means associated with the solid support that is specific for affixing an infecting bacterium that is causing the severe peripheral bacterial infection; circulating the patient's blood through the container, thereby cleansing the blood by removing at least a portion of the infecting bacterium; and returning the treated blood to the patient.

Matson et al teach methods of treating patients that have severe peripheral bacterial infection (sepsis, inflammatory mediator disease, systemic inflammatory response syndrome (SIRS), multiorgan system dysfunction syndrome (MODS) and multiorgan system failure (MOSF)) with an extracorporeal adsorption device that removes foreign agents such as viruses, organic toxins, inorganic toxins, parasites, pathogens and the like from a patients blood (see the Abstract). Matson et al teach that the ultrafiltered blood is re-transfused back into the patient (see the Abstract). Claim limitations such as "wherein any antibiotic treatment of the patient is curtailed until the infecting bacterial load has been lowered to an acceptable risk level" and "which the blood is monitored for the reduction in the level of bacteria after treatment" would be inherent in the teachings of the prior art. Matson et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claims 18-22, 24-28 and 30 are rejected under 35 U.S.C. 102(e) as anticipated by Bell et al, *(U.S. Patent No. 6,774,102 B1, published August 10, 2004).*

Claims 1-22, 24-28 and 30 are drawn to a method for treating a patient having a severe peripheral bacterial infection comprising connecting the patient's peripheral system to an extracorporeal adsorption container having an inlet means and an outlet means for circulating blood in a whole or separated form; a solid support disposed and confined within the container; and a binding means associated with the solid support that is specific for affixing an infecting bacterium that is causing the severe peripheral bacterial infection; circulating the patient's blood through the container, thereby cleansing the blood by removing at least a portion of the infecting bacterium; and returning the treated blood to the patient.

Bell et al teach methods of treating patients that have severe peripheral bacterial infection (septic shock) with an extracorporeal adsorption device that removes endotoxins and cytokine inducing substances from blood or plasma (see the Abstract). Bell et al teach that endotoxins are lipopolysaccharides from gram-negative bacteria

and are the leading causes of sepsis and septic shock (column 1). Bell et al teach that the method comprises the removal of endotoxin form the blood of a human or animal subject which comprises removing a portion of blood from the subject, contacting the blood with an adsorbent whereby the endotoxin binds to the adsorbent, then returning the blood to the subject. Bell et al teach that the method used in the invention is carried out in a continuous flow (column 4). Bell et all teach that the duration of treatment will depend upon the endotoxin concentration in the blood, the type of endotoxin present, the capacity of the adsorbent to clear the endotoxin, flow rate and the like, all of which can be monitored and adjusted (column 4). The claim limitation "wherein any antibiotic treatment of the patient is curtailed until the infecting bacterial load has been lowered to an acceptable risk level" would be inherent in the teachings of the prior art. Bell et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Pertinent Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure *(American Journal of Kidney Diseases, Nov 1997, Vol. 30, No.5, p. S44-S56 and Therapeutic Apheresis, Feb 2003, Vol. 7, No.1, pp. 108-114).*

Status of Claims

13. No claims are allowed.

Conclusion

14. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
September 13, 2004

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